Guidance for Industry and FDA

Guidance for Electrical Safety, Electromagnetic Compatibility and Mechanical Testing For Indwelling Blood Gas Analyzer Premarket Notification Submissions

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Division of Cardiovascular and Respiratory Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Christy Foreman, Center for Devices and Radiological Health, 9200 Corporate Boulevard, HFZ-450, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Christy Foreman at (301) 443-8609 extension 177.

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Guidance[1] for Electrical Safety, Electromagnetic Compatibility and Mechanical Testing For Indwelling Blood Gas Analyzer Premarket Notification Submissions

Purpose

This guidance document describes a means by which indwelling blood gas analyzers may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate indwelling blood gas analyzer device should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

This guidance document has been developed as a special control to support a change in classification from class III to class II. It identifies relevant material to include in a premarket notification. We intend it be used in conjunction with other identified special controls. All FDA requirements regarding premarket notification submissions are not repeated in this document. Please refer to the Federal Register notice published on March 15, 1999 for other applicable guidance documents and standards.

General Criteria and Testing

The premarket notification should include testing that demonstrates the performance characteristics of the device in the intended environment of use. The type of the device and its intended environment will determine the type of testing that is necessary. Recommended environmental, electrical, electromagnetic compatibility, and mechanical test procedures and protocols are discussed in the following sections.

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[1]This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Submit the following information in the premarket notification:

- test procedures and protocols
- test results
- an analysis of the results
- explanation of how test procedures simulate the intended environment of use
- explanation of how test procedures are comparable to the test procedures outlined below

If device failure occurs during the testing, show how failure does not affect safety or effectiveness. However, if the device has been modified in response to such failure, describe these modifications (including the identification of and rationale for each modification), and include follow-up testing results demonstrating that the modification alleviates the problem.

General Test Methods

Establish and use general test methods for verifying that device performance is within specification when subjected to the environmental testing procedures described in this document. Provide:

- description of the general test methods
- design of the tests used
- rationale for the tests used
- testing procedures and protocols,
- results
- analyses of the results

Unless otherwise specified, the test conditions should be as follows:

Temperature: 15 to 35°C
Humidity: 30 to 90 percent
Barometric pressure: 68 to 106 kPa
Line voltage: 110 V rms to 125 V rms

For modular devices, test in more than one typical module configuration with the other modules operating.

Visual and Audible Status Indicators (Alarms)

Test methods for visual and audible indicators (alarms) should conform to either

- ASTM: F1463-93(1999) Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care

Or

- Anesthesia and Respiratory Care Alarm Signals, Part 1: Visual Alarm Signals ISO 9703-1:1992 **and**
- Anesthesia and Respiratory Care Alarm Signals, Part 2: Auditory Alarm Signals ISO 9703-2:1994

Electrical Safety

Electrical Power Indicators

Power visual status indicators should be provided to indicate that the device is energized. Such indicators should be located conspicuously on the device.

Electrical Power Indicators Test Methods

Determine by inspection that visual status indicators indicate when the device is energized.

Overcurrent Protection

Overcurrent protection should be provided for all line-powered devices.

An audible warning status indicator should be activated if the overcurrent protection mechanism is activated and operation of the device cannot be operated. This status indicator (alarm) should be capable of sounding for at least 15 minutes.

Medical devices should not be fitted with protective mechanisms which may cause disconnection of the device from the power line (supply mains) by producing a short-circuit which results in operation of an overcurrent protection mechanism.

Overcurrent Protection Test Methods

For ac line-powered devices:

- Determine by inspection the presence of overcurrent protection.
- Activate the overcurrent protection mechanism. Record the time at which the audible warning status indicator activates and the time at which it ceases to sound. Failure of the alarm to activate or to sound for at least the time duration identified in the device specifications should constitute failure of this test.

- Operate from a power distribution strip that incorporates a slow-blow fuse or a circuit breaker appropriately rated for the device under test. Activate the device overcurrent protection mechanism. Activation of the power distribution strip fuse or circuit breaker should constitute failure of this test.

- Monitors should not be fitted with protective devices that may cause disconnection of the monitor from the power line (supply mains) by producing a short-circuit that results in the operation of an overcurrent protection device.

Dielectric Strength

Power source conductors, patient contact circuits, and transducer circuits should be adequately insulated to assure protection of the patient and device from over voltages.

Dielectric Strength Test Methods

Test for dielectric strength in accordance with IEC 60601-1, Clause 20 (1988).

AC Power Grounding and Polarity

If the device power connector is not polarized, the device should operate within its specification in both polarities of power line connector insertion.

AC Power Grounding and Polarity Test Methods

For ac line-powered devices:

- Determine by inspection the presence of overcurrent protection.

- Activate the overcurrent protection mechanism. Record the time at which the audible warning status indicator activates and the time at which it ceases to sound. Failure of the alarm to activate or to sound for at least the time duration identified in the device specifications should constitute failure of this test.

- Operate from a power distribution strip that incorporates a slow-blow fuse or a circuit breaker appropriately rated for the device under test. Activate the device overcurrent protection mechanism. Activation of the power distribution strip fuse or circuit breaker should constitute failure of this test.

- Monitors should not be fitted with protective devices that may cause disconnection of the monitor from the power line (supply mains) by producing a short-circuit that

results in the operation of an overcurrent protection device.

If the ac power connector is not polarized, reverse the polarity of the ac connection and repeat all tests.

Leakage Current

Provide the leakage current testing procedures and protocols, test results including leakage current measurements and identification of standards applied in testing in the premarket notification.

Leakage Current Test Methods

Test the device in accordance with IEC 60601-1 for Type BF equipment or in accordance with other applicable standards with leakage current specifications.

Auxiliary Output

Where an auxiliary output is provided:

- The device should operate within its specification during and after application of a short-circuit applied to the auxiliary output for 1 minute.
- The leakage current recommendations described in this document should not be exceeded upon proper connection of an auxiliary device to the auxiliary output. Describe proper connection in the operator's manual.

Auxiliary Output Test Methods

If the device is provided with an auxiliary output:

- This output should be short-circuited (all pins connected together) for at least 1 minute, with the device in the standard operating mode. During and after application of the short-circuit, the device should operate within its specification.
- With the auxiliary output connected as specified by the manufacturer, test as described under Leakage Current Test Methods

Electromagnetic Compatibility

Electromagnetic compatibility is described in IEC 60601-1-2 (1993) with the replacement and additional requirements contained Subclauses 6.8.201(a) (except for the reference to 36.201.1.3), (b) and (c). Address electromagnetic compatibility in the premarket notification by describing and testing the performance characteristics under all applicable circumstances when operating from grounded and ungrounded ac power sources (i.e., with the third-wire ground connected and with it disconnected at the plug end of the power cord).

Devices should be tested for electromagnetic emissions and immunity to electromagnetic interference as described herein. Devices should be tested with the third wire ground connected at the plug end of the power cord. Devices intended for home use should be tested with the third wire ground connected and with it disconnected at the plug end of the power cord.

Electromagnetic Energy Emissions

The device should operate within its specification without emitting electromagnetic energy in excess of the levels specified below. The emission limit should be that specified by the referenced document, adjusted downward by the rms sum of all errors in the measurement of that quantity.

Electromagnetic Energy Emissions Test Methods

Emissions measurements should be made as specified in the referenced document. The required emission limit should be that specified by the referenced document, adjusted downward by the rms sum of all errors in the measurement of that quantity. Emission in excess of the adjusted limit should constitute failure of this test. These tests should be conducted using passive patient simulators, which in general are not capable of simulating normal patient signals.

Radiated and Conducted Electromagnetic Energy

Demonstrate the performance characteristics of the device relative to the requirements of CISPR 11 when tested as recommended in this guidance document. Provide this information in the premarket notification.

Radiated and Conducted Electromagnetic Energy Test Methods

The device should be tested according to CISPR 11.

Magnetic Fields

Demonstrate the performance characteristics of the device relative to RE101 (Army, 7-cm distance) of MIL-STD-461D from 30 Hz to 100 kHz when tested at the 7-cm distance according to RE101 of MIL-STD-462D.

Magnetic Fields Test Methods

The device should be tested for radiated magnetic field emissions between 30 Hz and 100 kHz as specified in RE101 of MIL-STD-462D, using the Army 7-cm limit. Measure at the 7-cm distance only.

Immunity and Electromagnetic Interference

The device should operate within its specification during and after exposure to electromagnetic interference at the levels specified below. The immunity level should be the level stated, adjusted upward by the rms sum of all errors in the measurement of that quantity, with the exception of the lower steady-state ac voltage limit and the line-voltage sag level, which should be adjusted downward by the rms sum of the measurement errors. The device should not, as a result of the specified test condition: indicate an equipment alarm, exhibit temporary degradation or loss of function or performance which requires operator intervention or system reset, or exhibit loss or corruption of stored data.

Immunity of the device to electromagnetic interference should be determined as specified in the referenced document, with the modifications listed below. The immunity level should be the level stated, adjusted upward by the rms sum of all errors in the measurement of that quantity, with the exception of the lower steady-state ac voltage limit and the line-voltage sag level, which should be adjusted downward by the rms sum of the measurement errors. Any of the following should constitute failure of this test: an equipment alarm, temporary degradation or loss of function or performance which requires operator intervention or system reset, or loss or corruption of stored data. Patient simulators should be used to provide simulated normal stimulus to sensors during electromagnetic immunity testing.

Electrostatic Discharge

The device should operate within its specification within 5 seconds of air discharges of 2, 4, and 8 kV, both positive and negative, applied to insulating surfaces and contact discharges of 2, 4, and 6 kV, both positive and negative, applied to conductive surfaces, both positive and negative, to include any point on the device accessible to the operator or patient, without the use of a tool, when tested according to IEC 61000-4-2, as specified in section 4.2. The device should operate within its specification within 5 seconds of contact discharges applied to horizontal and vertical conducting planes in the vicinity of the device.

Electrostatic Discharge Test Methods

The device should be tested with air discharges at 2, 4, and 8 kV, both positive and negative, applied to insulating surfaces and contact discharges at 2, 4, and 6 kV, both positive and negative, applied to conductive surfaces. Failure to resume normal operation (with no operator intervention) within 5 seconds of a discharge should constitute failure of this test. All test failure conditions listed above apply. The device should be tested according to IEC 61000-4-2, with the following conditions and modifications:

- The device should be tested according to the test method described in IEC 61000-4-2 for table-top equipment
- The relative humidity should not exceed 50 percent during air discharges.
- Air discharges should be conducted at 2, 4, and 8 kV. Contact discharges should be conducted at 2, 4, and 6 kV. Discharges of both positive and negative polarity should be conducted at each voltage. At least 10 single discharges at each voltage and polarity should be applied to each test point
- In addition to air and contact discharges directly to the device, contact discharges should be made to the horizontal coupling plane under the device and to the vertical coupling plane positioned parallel to the faces of the device. At least 10 single discharges at each test voltage and polarity should be applied to each test point

Monitors that are internally powered IEC CLASS II or circuitry isolated from earth ground may be tested in a way that ensures that there is no appreciable charge retention between individual test discharges. The electrical potential of the monitor may be equalized with that of the ground plane, between individual test discharges, by temporarily attaching a ground strap incorporating two 470 kilowatt resistors connected in series. This potential equalization connected should be disconnected

and moved at least 1 meter away from the monitor during the application of individual test discharges.

Radiated Electromagnetic Fields

The device should operate within its specification during and after exposure to electromagnetic fields at frequencies between 80MHz and 2.5GHz at field (strengths up to 3 V/m (when unmodulated), amplitude modulated 80 percent with a 2 Hz sine wave or 100 percent with a square wave. A modulation frequency that is within each significant signal-processing passband of the device should used. For devices not having a defined passband, a modulation frequency of 0.5 Hz should be used. Specify the modulation frequency in the premarket notification.

Radiated Electromagnetic Fields Test Methods

Test conditions

The device should be tested for immunity to radiated electromagnetic energy over the frequency range 80 MHz to 2.5 GHz at a field strength of 3 V/m. The RF carrier should be amplitude modulated 80 percent by a sine wave or 100 percent with a square wave. A modulation frequency that is within each significant signal-processing passband of the device should be used. For devices not having a defined passband, a modulation frequency of 0.5 Hz should be used. The modulation frequency should be specified in the premarket notification.

If a continuous sweep of the test frequency is used, the sweep rate should not exceed 0.1 MHz/second. If the sweep is incremental, the step size should not exceed 1 MHz and the dwell time at each frequency should be 10 seconds.

Patient simulators used during the test should be either simple passive devices, isolated from earth ground using fiber optics or battery operated and shielded.

Connections not normally used during device operation that are made to the device to assess performance during the test should be isolated using fiber optics.

The radiated electric field should be linearly polarized. The test should be performed with both horizontal and vertical polarization.

A planar area of uniform field should be established that contains the front surface of all components of the device under test, including cables. The boundaries of the area of uniform field should include the maximum planar area occupied in any orientation of the parts of the device. The E-field should be measured at multiple points within the area of uniform field,

with all accessories and physical components of the device removed from the field.

Within the area of uniform field, the uniformity of the component of the electric field that is aligned with the intended E-field polarization should be -0, +6 dB, measured with no amplitude modulation present on the exposure field. At a minimum, point measurements should be performed at every incremental frequency in the 26 to 1000 MHz frequency range. E-field measurements should be made at uniformly spaced points throughout the entire surface of the area of uniform field for both horizontal and vertical polarization. The spacing between these points in both the vertical and horizontal directions should be 0.5 m or less. At each point, the component of the E-field that is aligned with the intended polarization should not differ from the total E-field at that point by more than 3 dB.

For a given facility, if placement of absorber, antennas, and area of uniform field are carefully reproduced, it should be necessary to map the area of uniform field only occasionally, e.g. once per year. Prior to a series of tests, the area of uniform field should be checked along a vertical line near the center, with measurements made at uniformly spaced points having a spacing of 0.5 m or less.

RF electric field instruments and measurement procedures should meet the requirements of ANSI/IEEE C95.3 - 1991. The instruments should not perturb the E-fields being measured by more than 2 dB and should measure local E-field strength with an error of less than ±3 dB over the frequency range of use. The field-sensing elements of the instrument should fit within a spherical volume with a diameter of 15 cm. The instrument should be capable of measuring the magnitude of each of the three orthogonal components of the electric field. In addition, the instrument should be capable of determining the total electric field strength (the square root of the sum of the squares of the three E-field vector components). The above measurements should be measured accurately (±1 dB) regardless of the direction of the radiated electric field (i.e., the field measuring instrument should be isotropic).

When practical, the test should be repeated with each of the six faces of the device facing the antenna. To the extent possible, all cables should be horizontal over the majority of their length throughout the test.

One or more of the following exposure methods should be used: (1) an open-area test site, with the signal and power leads fully extended horizontally; (2) an anechoic chamber; (3) a parallel-plate line; (4) a screen room; (5) a semi-anechoic chamber; or (6) a Transverse Electromagnetic (TEM) cell. In order to cover the entire frequency range, combinations of several exposure methods may be used over the portions of the range for which they are most appropriate. Where the methods yield different results, the open-site test should take precedence from 26 to 200 MHz and the anechoic chamber test should take precedence from 200 MHz to 1 GHz.

Test setup

When practical, all device components and cables should be elevated at least 0.8 m above any conducting ground plane by low dielectric constant (<2.5), nonconducting RF-transparent material. When this is not possible, device components should be mounted on a bulk non-conducting support at least 0.1 m high. All device components should be at least 0.8 m away from any RF-reflecting objects (e.g., walls of the exposure facility). The distance may need to be increased at certain frequencies to achieve field uniformity.

For exposure methods in which the device cables cannot be extended fully, if the length of any conducting cable is 1 m or less, it should be arranged horizontally in the planar area of uniform field. If the length of any conducting cable is greater than 1 m in length, up to the first three meters should be bundled in a serpentine configuration in the planar area of uniform. Conductive leads should be configured on a clean, dry, plastic foam (e.g., Styrofoam®) sheet with the dimensions and construction. Support pegs should be made of dielectric (e.g., Teflon®) rods (one-quarter inch in diameter). Cables in excess of 3 m should be bundled low-inductively and placed on the non-conducting support.

RF/EMI filters should be used at the device's ac power plug.

All cables should be arranged so that they are horizontal over the majority of their length throughout the test. Device cables 1 meter or less in length should be arranged horizontally in the planar area of uniform field. For cables greater than 1 meter and less than or equal to 3 meters in length, the cable should be bundled in a serpentine configuration in the planar area of uniform field. For device cables grater than 3 meters in length, the first 3 meters should be bundled in a serpentine configuration in the planar area of uniform field and the remainder should be bundled low-inductively an placed on the non-conductive support.

Patient simulators used during the test should be either simple passive devices isolated from ground using fiber optic links, or battery operated and shielded. If the frequency step dwell method is used, the frequency step size should not exceed 1 percent of the fundamental and the dwell time should not be sufficient to allow the device to respond to the test. The dwell time should be based on the modality with the slowest response time and should be at least 3 seconds.

For modalities that average data over time, the minimum dwell should be either 1.2 times the averaging period or 3 seconds, which ever is greater. If the averaging period is adjustable the averaging period used to determine dwell time should be the monitor’s default averaging period, the period. If there is no default averaging period, the period used should be that which is expected to be used most often in clinical applications of the device.

If the continuous frequency sweep method is used, the rate of sweep should not exceed (4.5/X) x 10000 decades per second. Connections not normally used during the operation on the device that are made to the device to access performance during the test should be isolated using fiber optic links.

AC Voltage Fluctuations, Transients, and Surges

The following items apply to all devices that operate from the ac power line:

Steady-state voltage

The device should operate within its specification, without changing a voltage selection switch, when powered from line voltages between 95 and 132 volts rms.

For monitors that operate directly from an ac power lines, demonstrate the performance characteristics during and after power line dips to:

- less than 1 % of nominal voltage for 0.5 cycle
- 40 % of nominal line voltage for 5 cycles
- 70% of nominal line voltage for 25 cycles of the power frequency

when tested according to IEC 61000-4-11.

For monitors that operate directly from an ac power line demonstrate the performance characteristics during and after power line dips to less than 1 % of nominal line voltage for 15 seconds according to IEC 61000-4-11. Test voltages should be step changes and start at a zero crossing.

Dropout

The device should operate within its specification during and after line voltage dropouts for durations of 10 milliseconds and less.

Slow sags and surges

The device should operate within its specification during and after line voltage surges to 150 V rms and sags to 90 V rms for durations of 500 ms and less.

Fast transient bursts

The device should operate within its specification during and after bursts of transients of 0.5, 1, and 2 kV, positive and negative, applied to ac power leads and transients of 0.25, 0.5, and 1 kV, both positive and negative coupled by way of a capacitive clamp to signal and interconnecting leads, that are specified to be 3 meters or more in length when tested according to IEC 61000-4-4, with the exception that the burst repetition frequency should not exceed 30 per minute.

The pulse repetition rate should be 5 kHz. Patient cables should not be tested directly, but should be attached to the monitor during the testing of all other cables power lines. Application of test to power lines should only be made simultaneously with respect to the ground reference plane.

Demonstrate the performance characteristics of the monitor during and after application of surges of 0.5, 1, and 2 kilovolts, both positive and negative, between ac power line(s) and ground, and application of 0.5 and 1 kilovolt, both positive and negative, between ac power line(s) (line-to-line), when tested according to IEC 61000-4-5. All other monitor cables should not be tested directly. Describe the response of the monitor to each individual surge.

While only power lines are tested, all monitor cables should be attached during the test. Five surges at each voltage level and polarity should be applied to each power line at each of the following: positive and negative zero crossing and positive and negative peak of the ac voltage waveform.

While only power lines are being tested, all device cables should be attached during the test.

Five surges at each voltage level and polarity should be applied to each power line at each of the following:

- the positive and negative zero crossing
- the positive and negative peak of the ac voltage wave worm

AC Voltage Fluctuations, Transients, and Surges Test Methods

The tests described below should be performed on all devices that operate from the ac power line.

Steady-state voltage

Raise the line voltage to 132 volts rms and allow the device to stabilize. Test device operation according to sections (k) and (l). Repeat for a voltage of 95 volts rms.

Dropout

Operate the device at 95 volts rms, lower the line voltage to 0 volts for 10 milliseconds, and then restore it to 95 volts rms, doing so 10 times at a rate not to exceed 30 per minute.

Slow sags and surges

Operate the device at 120 volts rms. Raise the line voltage to 150 volts rms for 500 ms. Repeat at 10-second intervals for a total of 10 times. Again operate the device at 120 volts rms. Lower the line voltage to 90 volts rms for 500 ms. Repeat at 10-second intervals for a total of 10 times.

Fast transient bursts

Test ac power leads and signal leads according to IEC 61000-4-4 for type test of table-top equipment, with the exception that the burst repetition frequency should not exceed 30 per minute. Test supply leads at 0.5, 1, and 2 kV, and signal leads at 0.25, 0.5, and 1 kV.

Fast surges

Test generator

The values of elements R_{s1}, R_{s2}, R_m, L_r, and C_c are such that the generator delivers at a single output a combination voltage/current wave characterized by a 1.2/50 µs voltage surge when measured across a high-resistance load (more than 100 ohms) and a 8/20 µs current surge when measured into a short-circuit, i.e. the generator has an effective output impedance of 2 ohms.

The generator should be capable of producing an open circuit output voltage of up to 2 kV, both positive and negative polarity, with wave. The generator should be capable of delivering short-circuit output current of at least 1 kA.

The generator should be triggerable so that the phase angle of the discharge can be set at 0, 90, 180, and 270 degrees with respect to the ac line voltage.

Test setup

Capacitive coupling should be used to apply the combination wave to the ac power leads of the device under test.

A decoupling network should be used to isolate the device under test from the ac power network. Residual test pulse voltage on unsurged leads should not exceed 15 percent of the maximum applied test voltage when the device is disconnected. Residual test pulse voltage on the inputs of the decoupling network when the device and the power supply network are disconnected should not exceed 10 percent of the applied test voltage or twice the peak value of the power line voltage, whichever is greater.

Surges should be applied at the point where the device would normally be connected to ac line power.

For the line-to-line test, an 18 uF coupling capacitor should be used.

For the line-to-ground tests, a 10 ohm resistor should be used in series with the test generator and a 9 uF coupling capacitor should be used.

Test procedure

The line-to-line test should be performed using 1 kV surges of both positive and negative polarity applied using a generator source impedance of 2 ohms and coupling capacitance of 18 uF with the generator output floating.

The line-to-ground test should be performed using 2 kV surges of both positive and negative polarity applied using a generator source impedance of 12 ohms and coupling capacitance of 9 uF with the generator output grounded. The test should be repeated with surges applied successively between each line and ground.

Surges at each amplitude and polarity should be applied at phase angles of 0, 90, 180, and 270 degrees with respect to the ac line.

Each test should be repeated 10 times at a rate of 1 surge per minute.

Conducted Electromagnetic Energy

The device should operate within its specification during and after exposure of each interconnecting cable, including power cables, to conducted electromagnetic energy at frequencies between 10 kHz and 100 MHz at the levels specified in CS114, Curve #3, of MIL-STD-461D, when tested according to CS114 of MIL-STD-462D. A modulation frequency that is within each significant signal-processing passband of the device should be used. For devices not having a defined passband, a modulation frequency of 0.5 Hz should be used. The modulation frequency should be specified in the premarket notification.

Test the monitor should during and after exposure to conducted electromagnetic energy at 3 volts rms (measured before modulation is applied), modulated 80 percent with a 2 Hz sine wave over the frequency range beginning at the start frequency specified below and extending to 80 MHz when tested according to IEC 61000-4-6.

Conducted Electromagnetic Energy Test Methods

The device should be tested for immunity to conducted electromagnetic energy on each power and signal lead at frequencies between 10 kHz and 100 MHz at the levels specified in curve #3 of CS114 of MIL-STD-461D, using the test methods specified in CS114 of MIL-STD-462D, with the modifications and additions listed below.

- If continuous sweep of the test frequency is used, the sweep rate should not exceed 1 x 10^{-3} decades/second. If the sweep is incremental, the step size should not exceed 1 percent of decade, and the minimum dwell time is 10 seconds per step.

- A modulation frequency that is within each significant signal-processing passband of the device should be used. For devices not having a defined passband, a modulation frequency of 0.5 Hz should be used.

- The leads under test should be elevated 5 cm above the ground plane.

- For power cables, the interference signal should be injected at a distance of 5 cm from the point at which ac line power enters the device.

Test conditions as described in subclause 36.202.5:

- Sine wave amplitude modulation at 80 percent depth and a frequency of 2 Hz should be used.

- For power input lines and the equipotential ground connection, if provided, the start frequency should be 150 kHz.

- For every cable that can be connected to the monitor, other than power lines, the start frequency should be determined from the guidance given in IEC 61000-4-6, Annex B, Figure B.1, based upon the longest allowed cable length specified by the manufacturer. If the longest cable length is not specified, the start frequency should be 150 kHz.

- Equipotential ground connections should be tested using an M1 coupling/decoupling network (CDN) as specified in IEC 61000-4-6, Annex D, Figure D.2.

- Patient cables should be tested using a current clamp. The patient end of the coupled cables that provide a conductive connection to the patient should be terminated so that the impedance between the monitor and the ground reference plane is between 105 and 190 ohms over the frequency range 150 kHz and 80 MHz. No intentional decoupling device should be used between the injection point and the patient coupling point. An artificial hand is specified in CISPR 14 should be applied to the patient end of the patient coupled cables. If required for proper operation of the monitor, an insulating material with a thickness of 5 millimeters or less may be applied between the metal foil of the artificial hand and the patient coupling point.

- If the frequency step and dwell method is used, the frequency step size should not exceed 1 percent of the fundamental and the minimum dwell time should be sufficient to allow the monitor to respond to the test signal. The dwell time should be based on the modality with the slowest response time and should be at least 3 seconds. For modalities that average data overtime, the dwell time should be either 1.2 times the averaging period or 3 seconds, whichever is greater. If the averaging period is adjustable, the averaging period used to determine dwell time should be the monitor's default averaging period. If there is no default averaging period, the period used should be that which is expected to be used most often in clinical applications of the monitor.

- If the continuous frequency sweep method is used, the rate of the sweep should not exceed (4.5/X) x 10000 decades per second, where X is the dwell time in seconds, determined as specified in the section above.

- Calibration of current injection clamps should be performed in a 150 ohm system

Magnetic Fields

A modulation frequency that is within each significant signal-processing passband of the device should be used. For devices not having a defined passband, a modulation frequency of 0.5 Hz should be used. The modulation frequency should be specified in the premarket notification.

Demonstrate the performance characteristics of the monitor during and after exposure to 60 Hz

continuous wave magnetic fields at 3 amperes per meter when tested according to IEC 61000-4-8, with the exception that a maximum display jitter of 0.6 millimeters is allowed for cathode ray tube displays.

Monitors that recharge batteries or operate from an ac power line should be powered at a line frequency of 60 Hz during the test.

Magnetic Fields Test Methods

Demonstrate the performance characteristics of the monitor during and after exposure to 60 Hz continuous wave magnetic fields at 3 amperes per meter when tested according to IEC 61000-4-8, with the exception that a maximum display jitter of 0.6 millimeters is allowed for cathode ray tube displays.

Quasi-static Electric Fields

Demonstrate that the device operates within its specification during and after exposure to a sinusoidally varying electric field at 0.5 Hz with peak field strengths up to 2000 volts per meter. Note: This test simulates the movement of electrostatically charged fabrics and objects that could come into close proximity to the device.

Quasi-static Electric Fields Test Methods

Test setup

The device should be tested between parallel horizontal planes. They should be metallic sheets (copper or aluminum) of 0.25 mm minimum thickness which extend at least 0.1 m beyond the device. The horizontal planes should be separated by insulating material, with a separation at least three times the height of the device in the position of normal use.

The device should be supported by insulating material so that it is positioned entirely between 1/3 and 2/3 the distance between the horizontal planes.

Cables and tubing should be supported by insulating material at a height above the bottom horizontal plane of 1/3 the distance between the planes and should exit the test apparatus and continue at this height for at least 0.1 meter beyond the horizontal planes.

The output of a signal generator capable of producing a sinusoidally varying voltage at a frequency of 0.5 Hz with amplitude sufficient to produce peak electric field strengths up to 2000 V/m between the horizontal planes should be connected to the horizontal planes.

Note: $E_p = V_p/D$, where E_p is the peak field strength in V/m, V_p is the peak of the signal generator output voltage waveform, and D is the distance between the horizontal planes in meters.

Test procedure

Adjust the signal generator peak output voltage such that the device is exposed to a sinusoidally varying electric field at 0.5 Hz with peak field strength of 500 V/m. Gradually increase the peak field strength to 2000 V/m.

Voltage Dips

Voltage dips are defined as short interruptions and voltage variations on power supply input lines.

Voltage Dips Test Methods

For devices that recharge batteries from the ac power line and devices that operate from the ac power line, demonstrate the performance characteristics during and after power line dips to less that 1 percent of nominal line voltage for 0.5 cycle, to 40 percent of nominal line voltage for 5 cycles, and to 70 percent of nominal line voltage for 25 cycles of the power frequency, when tested according to IEC 61000-4-11.

For monitors that recharge batteries from an ac power line and devices that operate directly from an ac power line, demonstrate the performance characteristics within 5 seconds after a power line dip to less than 1 percent of nominal line voltage for 15 seconds, when tested according to IEC 61000-4-1.

Test voltages changes should be step changes and start at a zero crossing.

For devices that recharge batteries from the ac power line and devices that operate from the ac power line demonstrate performance characteristics, without changing a voltage selection switch when powered from line voltage between 95 and 132 volts rms.

Environmental and Mechanical Safety

Controls Protection

The controls of medical devices should be protected from inadvertent or unauthorized changes or adjustment. The means of protection should be such as to preclude their defeat by patients, or other unauthorized persons.

All controls which increase or decrease a function should be marked with a legible indication to

inform the operator which action(s) is (are) required to increase/decrease the controlled function. Controls and their associated markings should be visible or legible, or both, to an operator having a visual acuity of at least 1.0 when the operator is located at least 1 meter in front of the device and the ambient illuminance level is 215 lux, when viewing the information, marking, etc. perpendicular to, and including 15 degrees above, below, left and right. Controls should be identified with their associated markings.

For controls, movement upward, to the right, or in a clockwise direction should increase the control function. Movement downward, to the left, or a counterclockwise direction should decrease the control function. Rotary gas flow controls are exempt from this performance criterion.

Controls Protection Test Methods

Test by inspection.

Connector Protective Incompatibility

Device connectors, including those on wires and tubing, should be designed such that insertion into a receptacle other than the one into which they are intended to be inserted or into a receptacle using an improper orientation should not be possible.

Electrical connectors of a device (e.g., electrical lead wires) should include a mechanism to prevent connection of the patient to a power source that may cause a current flow in excess of that specified in paragraph (h)(6).

Electrode lead wires and patient cables for use with a medical device must comply with 21 CFR §898.12, Performance Standard for Electrode Lead Wires and Patient Cables.

Connector Protective Incompatibility Test Methods

Test by inspection and by attempting the prohibited connections.

Mechanical Safety

Each device should:

- not have any exposed sharp edges
- be mechanically stable in the intended position(s) of use
- provide protection to the operator and patient from moving parts

Mechanical Safety Test Methods

Test by inspection.

Mechanical Vibration and Shock Resistance

The device (i.e., the complete system suitable for its intended use) should withstand the mechanical shocks and vibrations expected in the environments of intended use as defined by the test methods contained herein, and should remain operational within its specification. Demonstrate the performance characteristics of the monitor following mechanical shock and vibration when tested according to IEC 60068-2-32 free fall procedure.

Mechanical Vibration and Shock Resistance Test Methods

Test the device (i.e., the complete system suitable for its intended use) to the following severity levels as specified in the following procedures. After each of these tests, visually inspect the device. Any evidence of damage or inability to perform within specification constitutes failure of the test.

IEC 68-2-27: Shock

- Peak acceleration: 100 g (980 m/s^2)
- Duration: 6 msec
- Pulse shape: half sine

IEC 60068-2-32 Shock Test (Free Fall)

- Height: 0:5m
- Duration at attitude: 2 falls on each face

IEC 60068-2-64 Broad Band Random Vibration Test

- Frequency range 10 to 150 Hz,
- Acceleration spectral density: 1(meter per second squared) squared per hertz (g^2/Hz) from 10 to 12 Hz, decreasing at a rate of 3 decibels per octave from 12 to 150 Hz.
- Duration: 30 minutes on each orthogonal axis

IEC 60068-2-6 Sinusoidal Vibration

- Frequency range: 10 to 500 Hz
- Acceleration amplitude: 1 g (9.8 m/s^2)
- Type and duration of endurance: 10 sweep cycles in each axis.

IEC 68-2-34 Random Vibration, Wide Band

- Frequency range: 20 Hz - 500 Hz
- Acceleration spectral density: 0.02 g^2/Hz
- Degree of reproducibility: low
- Duration of conditioning: 9 minutes

Fluid Spill Resistance

The device should be so constructed that it continues to operate within its specification after fluids have been dripped on the device. Please refer to the requirements for drip-proof equipment as specified in Clause 44.6 of IEC 60601-1 and IEC 60529.

Fluid Spill Resistance Test Methods

Test the device as specified in Clause 44.6 of IEC 60601-1 according to the test method in IEC 60529 for drip-proof equipment. Following each of these tests, the device should be visually inspected. Any evidence of damage or inability to perform within specification constitutes failure of the test.

Temperature and Humidity

The device should operate within its specification when operating in the environmental temperature range of 5°C to 40°C, and in the environmental humidity range of 15 percent to 95 percent, noncondensing.

The device should not be damaged and should remain operational within its specification after storage in the environmental temperature range of minus 40°C to 70°C and at relative humidity up to 95 percent, non-condensing.

Temperature and Humidity Test Methods

Test the device as specified in Method Numbers 501.3, 502.3, and 507.3 of MIL-STD-810E. Failure of the device to perform within its specification constitutes failure of these tests.

Surface Temperature

Temperature of surfaces of a device an operator can contact during operation should not exceed 50°C in an ambient temperature of 35°C. The temperature of surfaces that may come in contact with the patient should not exceed 41°C in an ambient temperature of 35°C. Any surface that may come in contact with the patient exceeding 41°C, should be justified with a scientifically valid explanation and data should be provided demonstrating that patient safety is not compromised.

Surface Temperature Test Methods

Operate the device in an ambient temperature of 35°C. Measure the temperature of the device surfaces which are not intended to contact the patient. The presence of any temperature greater than 50°C should constitute failure of this test. Measure the temperature of device surfaces which are likely to contact the patient in normal use. Any temperature above 41°C should constitute failure of this test.

Toxic Materials

No toxic material from a device should come in contact with patient or operator during normal use.

Toxic Materials Test Methods

Determine by inspection that listed and any other known toxic materials used in the device are packaged in a manner that prevents patient and operator contact.

Strangulation

Provision should be made in routing, retention devices, or other means to minimize the risk of strangulation of the patient by wires or tubing. This may also be accomplished by providing instructions for routing of patient wires and tubing in the device labeling.

Strangulation Test Methods

Test by inspection.